“In America and around the world, systems supposed to help with patient care have proven unsafe, ineffective, or biased.” WH.gov

“Blueprint for an AI Bill of Rights”
https://www.whitehouse.gov/ostp/ai-bill-of-rights/

A primary example of the weaponization of algorithms and data collection creating a hostile regulatory environment for physicians, pharmacists and patients contributing to unconstitutional surveillance, prosecution, civil asset forfeiture, criminal incarceration, discrimination of patients, patient abandonment, denial of indicated medical care, poor clinical outcomes including medical complications, patient harm & death, as a result of failed public health policy is the direct correlation to the introduction of the Prescription Drug Monitoring Program (PDMP) created by Bamboo Health-formerly Apriss, and the secret proprietary algorithms that are not currently subject to regulation by the federal government- as a clinical decision making tool, but instead these proprietary algorithms have been utilized as a unregulated law enforcement tool, criminalizing the practice of medicine, and creating gaps in patient access to medical care.

PDMP as a Clinical Decision Making Tool
“The objective was to minimize harmful and illegal use and diversion of prescription medications, without interfering with their appropriate medical use. Advances in technology have enabled PDMPs to take on another important role— that of an adjunct source of information that prescribers and pharmacists can use to improve the care and safety of individual patients. Helping healthcare providers make the most informed prescribing and dispensing decisions, as part of an initiative to address opioid-related overdoses and deaths, is a federal government priority.”

https://store.samhsa.gov/sites/default/files/d7/priv/sma16-4997.pdf

As such, PDMP algorithms should be regulated with complete public transparency as a clinical decision making tool by the Federal Drug Administration (FDA). It should not be considered a tool for prosecution of physicians by law enforcement.

Center for US Policy
Center for U.S. Policy petition addressing the impact of Bamboo Health's NarxCare algorithms be classified a medical device subject to (FDA) regulation as a clinical decision making tool, or should be removed entirely from the market. Bamboo Health’s NarxCare algorithms are used in half of states, these algorithms have altered the practice of medicine and denied patient access to vital medication.

US Center for Policy
“CUSP/ FDA Citizen Petition to Protect Patients”
April 28, 2023
(21 pg.)

https://centerforuspolicy.org/fdacp2023-2/

“FDA weighs when software becomes a medical device”
May 26, 2023
Axios
“The Center for U.S. Policy says Bamboo Health's NarxCare should be classified a medical device and subject to regulation, because of the way it helps doctors and other providers decide if a patient should get painkillers.
In its citizen petition, the center writes that NarxCare — which is used in over half of the states — has "altered the practice of medicine" and denied patients access to potentially necessary treatments. The center is urging that NarxCare be declared a misbranded medical device and be pulled from the market.
Appriss Health, which first developed NarxCare, previously had information that said that some of the data *NarxCare evaluates included a patient's criminal history, electronic health records and medical claims data.*
It's unclear how much providers rely on NarxCare's scores, but the FDA — without explicitly mentioning Bamboo's software — *raised concerns around automation bias in its guidance, saying that providers can have a propensity to "over-rely on a suggestion from an automated system. The FDA would have to decide whether it has a specific oversight over the software, or potentially say that NarxCare falls under state jurisdiction under the argument that it enables state-run PDMPs.”*

https://www.axios.com/2023/05/26/fda-weighs-when-software-medical-device

The FDA has moral and ethical duty to regulate the PDMP as a “clinical decision making tool” ie; medical device and not further harm physicians, pharmacists or patients by handing regulatory oversight to the States, as an overarching “arm of law enforcement” further codifying the criminalization of the practice of medicine, creating gaps in patient access to medical care & further marginalizing vulnerable patient populations.

Legal Analysis of PDMP Discrimination and Harm
“Dosing Discrimination: Regulating PDMP Risk Scores”
110 California Law Review 47 (2022)
69 Pages PDF Download
Posted: 19 Jan 2021
Last revised: 2 Mar 2022
Professor Jennifer D. Oliva
UC Law, San Francisco; O’Neill Institute for National & Global Health Law at Georgetown Law
Summary

“The proxies that PDMPs utilize to calculate patient risk scores likely produce artificially inflated scores for marginalized patients, including women and racial minorities with complex, pain-related conditions; poor, uninsured, under-insured, and rural individuals; and patients with co-morbid disabilities or diseases, including substance use disorder and mental health conditions.

Law enforcement conducts dragnet sweeps of PDMP data to target providers that the platform characterizes as “overprescribers” and patients that it deems as high risk of drug diversion, misuse, and overdose. Research demonstrates that PDMP risk scoring coerces clinicians to force medication tapering, discontinue prescriptions, and even abandon patients without regard for the catastrophic collateral consequences that attend to those treatment decisions. PDMPs, therefore, have the potential to exacerbate discrimination against patients with complex and stigmatized medical conditions by generating flawed, short-cut assessment tools that incentivize providers to deny these patients indicated treatment. The Federal Food and Drug Administration (FDA) is authorized to regulate PDMP predictive diagnostic software platforms as medical devices, and the agency recently issued guidance that provides a framework for such oversight. Thus far, however, the FDA has failed to regulate PDMP platforms. This Article contends that the FDA should exercise its regulatory authority over PDMP risk scoring software to ensure that such predictive diagnostic tools are safe and effective for patients**.”**

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3768774

“Prescription Drug Monitoring Programs and NarxCare with Attorney Jennifer D. Oliva”
Doctor Patient Forum
https://open.spotify.com/episode/6nxQqwSblRxS08hzk41pp4?si=xZFmaHzdSsSBCfDQdmrxkw&context=spotify%3Ashow%3A1ETxXiEg9aAjGyHcgH5XhB

Role of SCOTUS Ruling:
Ruan vs. United States and the PDMP
SCOTUS Ruling
“Ruan v. United States”
Practicing medicine in “good faith” addressing criminal law, the “opioid crisis narrative,” and multiple intersections within the provision of healthcare.

Hannah Miller & co-host Professor Patricia Zettler interview Professor Jennifer D. Oliva & Professor Kellie Gillespie.
5/15/2023

https://www.youtube.com/watch?v=tJZB203-f54

How Practice of Medicine is Criminalized, Contributes to Unconstitutional Incarceration through Surveillance and Discriminates
“How algorithms are being utilized as “government protocol for choosing doctors to attack, how they created junk science including criminal forensics tool that has no reliability or validity verification- physicians are going to prison & patients are being denied clinically indicated medications.”

https://youtu.be/fX1UljSLht8

“List of Doctors/ Professionals/ Family Members/ Office Staff Who Have Spent Time in Prison for Treating Pain”
Doctors of Courage
Last Modified April 26, 2023

https://doctorsofcourage.org/professionals-attacked/incarcerated/

Harm Related to Framing Complex Patients as Liability for Risk Mitigation
PDMP is not the only surveillance algorithms patients and the public at large should be questioning.
Never mind inherent bias, potential discrimination, unwarranted surveillance or pending medical complications & preventable deaths for complex patients via risk mitigation.

“How your health information is sold and turned into ‘risk scores’”
Politico
02/03/2019

“Companies are starting to sell “risk scores” to doctors, insurers and hospitals to identify patients at risk of opioid addiction or overdose, *without patient consent* and *with little regulation of the kinds of personal information used to create the scores.”*

“FICO® Medication Adherence Score”

https://www.fico.com/en/resource-access/download/3317

Fatal Patient Outcomes:A Result of Draconian Surveillance
DEA’s suspension of a California doctor’s license to prescribe opioids and other controlled substances lead to multiple preventable patient deaths.

“DEA Suspension of Doctor’s License Leads to Double Suicide”
November 09, 2022
By Pat Anson

“Second Patient Dies After DEA’s Suspension of Doctor’s License”
December 15, 2022
By Pat Anson

https://www.painnewsnetwork.org/stories/tag/Danny+Elliott

Trash In, Trash Out
Currently, statistical analysis does not support an overarching draconian & punitive surveillance approach method to surveil physician prescribing habits.
The public are currently overdosing on fatally potent illicit drugs and polypharmacy, a result of the iron law of prohibition, not safe, FDA approved, legally prescribed medication under a

physician's supervision. Further surveillance has not saved lives, but instead surveillance via proprietary algorithms puts lives in jeopardy.

"Estimates of Drug Overdose Deaths Involving Fentanyl, Methamphetamine, Cocaine, Heroin, and Oxycodone: United States, 2021"
Merianne Rose Spencer, M.P.H., Margaret Warner, Ph.D., Jodi A. Cisewski, M.P.H., Arialdi Miniño, M.P.H., David Dodds, Janaka Perera, and Farida B. Ahmad, M.P.H.

https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/645563490577ef7a0ee337fe/1683317577574/CDC+overdoses.pdf

PDMPs were established on the mistaken idea that prescribed opioids contribute to abuse and overdose deaths. This is a popular, but dangerous mistaken narrative.

"Today's nonmedical opioid users are not yesterday's patients; implications of data indicating stable rates of nonmedical use and pain reliever use disorder"
Jeffrey A Singer, Jacob Z Sullum, Michael E Schatman

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6369835/

Risks of AI Concern Experts
Statement on AI Risk
AI experts and public figures express their concern about AI risk.
"AI experts, journalists, policymakers, and the public are increasingly discussing a broad spectrum of important and urgent risks from AI. Even so, it can be difficult to voice concerns about some of advanced AI's most severe risks. The succinct statement below aims to overcome this obstacle and open up discussion. It is also meant to create common knowledge of the growing number of experts and public figures who also take some of advanced AI's most severe risks seriously."

https://www.safe.ai/statement-on-ai-risk#signatories

Prevailing Question
How has undue, unwarranted surveillance of patients and physicians using data collection, predictive algorithms undermine the patient-physician relationship and criminalize the practice of medicine, leading to denial of medical care, failed public health policy, patient harm, violations of patient physician civil and human rights?
If the government intends to restore faith in it's federal agencies, this question can not be sidelined.

Summary
If your federal initiative entails "Advancing trustworthy Artificial Intelligence ("AI") is an important federal objective:

[1] The National AI Initiative Act of 2020 [2] established federal priorities for AI, creating the National AI Initiative Office to coordinate federal efforts to advance trustworthy AI applications, research, and U.S. leadership in the development and use of trustworthy AI in the public and private sectors-

it is time to fully examine with transparency, bring oversight reforms regarding secret corporate proprietary algorithms and data collection utilized as tools of “surveillance” to develop public health policy to mitigate risk implemented across all sectors of healthcare.

It is crucial that there is public transparency & FDA federal government oversight mechanisms put into place, to fully weigh the subsequent negative and harmful impact of “clinical decision making tools” being used as “surveillance tools by law enforcement” as weaponized prosecutorial methods in a failed war on illicit drug trafficking to surveil both physicians & patients to prevent further public harm.